

**Responses to comments submitted on behalf of the Battery Council International and by King and Spalding for the Lead Industries Association, Inc.**

**General comments: Lead should not be included in Tier 1.**

**Comment 1:** Lead is already undergoing review on the exact same basis, as part of an ongoing proceeding under California Health and Safety Code sections 39660 *et seq.*, the net result of which will be the imposition of additional air emission control measures if needed to protect children's health. Accordingly, listing lead as a Tier 1 TAC under the current initiative is duplicative and unnecessary.

**Response 1:** OEHHA has been charged with prioritizing identified TACs irrespective of their consideration in other processes. The inclusion of lead in Tier 1 reflects the high level of concern OEHHA associates with lead based on the best available science. The listing of lead under SB 25 is complementary to the process that ARB is going through for risk management, and is not duplicative. ARB just completed an analysis of how to look at risks from lead exposure (in consultation with OEHHA) as part of their Risk Management Guidelines. The next step is to decide what control measures they can devise. This listing complements that process in that it indicates that the control measures should include considerations of impacts on children. It isn't duplicative or unnecessary as indicated in the comment.

**Comment 2:** The OEHHA document on lead included in the draft prioritization document relies overwhelmingly on the OEHHA 1997 document, and no new rationale for concern is provided that would suggest a justification for duplicating that effort. Indeed, as the OEHHA 2001 document makes clear, ambient air lead levels in California have dropped since OEHHA's 1997 review -- 0.014  $\mu\text{g}/\text{m}^3$  in 1999, compared to 0.06  $\mu\text{g}/\text{m}^3$  in the 1997 ARB report. Past history would suggest that these levels will continue to decline.

**Response 2:** As indicated in the response to comment 1, OEHHA is charged with prioritizing TACs based on the best and most current science, including studies published since 1997. We are not being duplicative of ARB's efforts because we are not evaluating risk management options.

There is suggestion in the more recent studies that lead's adverse effects may occur at lower levels than previously thought. For example, Campagna *et al.* (2000)<sup>1</sup> reported that erythrocyte calcium pump activity in human maternal and fetal cord blood was inhibited by lead at levels of 6.3 and 4.8  $\mu\text{g}/\text{dL}$ , respectively. Similarly, Rothenberg *et al.* (2000)<sup>2</sup> found maternal blood lead levels (BLL) as low as 7.7  $\mu\text{g}/\text{dL}$  associated with changes in the brainstem auditory evoked response in children at 1 month and again at 5-7 years of age. These effects were seen at levels below CDC's 10  $\mu\text{g}/\text{dL}$  threshold of concern. OEHHA acknowledges that ambient air lead

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<sup>1</sup> Campagna D., Huel G., Hellier G., Girard F., Sahuquillo J., Fagot-Campagna A., Blot P. 2000. Negative relationships between erythrocyte Ca-pump activity and lead levels in mothers and newborns. *Life Sci.* 68:203-15.

<sup>2</sup> Rothenberg S., Poblano A., Schnaas L. 2000. Brainstem auditory evoked response at five years and prenatal and postnatal blood lead. *Neurotoxicol Teratol* 22:503-10.

levels have shown dramatic decreases in the past several years, largely due to the removal of lead from gasoline. As a result, the contribution by stationary sources has become more prominent. On page 6 of the draft document, OEHHA has calculated that 45% of the one- and two-year old children, if exposed to the current ambient air standard of  $1.5 \mu\text{g}/\text{m}^3$  which might be expected in the vicinity of stationary sources, would have BLLs above CDC's  $10 \mu\text{g}/\text{dL}$  threshold.

**Comment 3:** In December 2000, the CDC announced that geometric mean blood lead levels in children aged 1-5 years decreased from the  $2.7 \mu\text{g}/\text{dL}$  reported in 1997 to a new low of  $2.0 \mu\text{g}/\text{dL}$  for data collected in 1999. Data collected for the Western Region of the U.S. -- which includes California -- in NHANES III indicate even lower levels than the national average.

**Response 3:** The cited CDC report also includes the following qualification: "Despite the overall decline in average BLLs, CBLs data show that the risk for elevated BLLs in children tested remains high in some counties and varies greatly among and within states. This variation most likely reflects geographic variation in the prevalence of risk factors for elevated BLLs such as residence in older housing and poverty." (CDC MMWR 49 (5) 1133-7 Dec 22, 2000) An additional risk factor is living in proximity to stationary sources of air lead emissions.

**Comment 4:** The OEHHA prioritization document places great emphasis on evidence of decreasing exposures in downgrading substances to Tier 2. Other substances are assigned to Tier 2 rather than Tier 1 because of lack of data. It is difficult to understand why these considerations would not dictate assigning a lower priority level to lead, a substance as to which data are well documented, both airborne exposures and blood lead levels have dropped substantially and are continuing to fall, and an ongoing proceeding is already examining these same issues with a view to determining if additional air emissions control measures are needed.

**Response 4:** OEHHA agrees that there is a large and persuasive body of data regarding lead, so lack of data is not a reason to assign it to Tier 2. While lead levels in air and blood have been dropping, it has not been possible to demonstrate a threshold BLL below which there are no adverse effects. OEHHA considered this fact in the context of the demonstrable adverse effects of lead when making its tier assignments.

**Comment 5:** Surely, scarce regulatory resources would be better directed toward substances that pose increasing risks or lack data, and accordingly pose an unknown and perhaps greater magnitude of threat to children.

**Response 5:** Rectifying data gaps is an on-going process and it is OEHHA's position that substances of known substantial health risks take priority over substances of lower or unknown risk. As mentioned in the response to comment 3 and 4, the magnitude of lead's health effects coupled with the lack of a known threshold for adverse effects were major considerations in its inclusion in Tier 1.